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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,970	08/29/2001	Ashok Rampal	RLL-170US	7742

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,970	RAMPAL ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Al-Razzak et al (USPN 6010718). Claim 11 is drawn to a monolithic dosage of clarithromycin comprising 100-1000 mg of clarithromycin when the total dosage is not more than 1500 mg. Al-Razzak discloses a dosage of 500 mg of clarithromycin in a 900 mg tablet (Example 1). The reference teaches a tablet well within the claimed range of the applicant. These disclosures leave the claimed invention anticipated.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10 and 12 are all rejected under 35 U.S.C. 103(a) as being unpatentable over Balkin (USPN 5656284) in view of Urquhart et al (USPN 4851232). Claims 1-6 are drawn to a controlled release formulation comprising erythromycin (or a derivative thereof) and a controlled release polymer from 0.1% to 4% w/w of total composition. Claim 2 goes on to recite that the derivative thereof is clarithromycin. Claims 3 and 4 specify specifically what concentration of the medicament is being claimed. Claim 5 and 6 give specifics on the rate-controlling polymer with 5 listing possibilities and 6 specifying which carbohydrate gums are acceptable.

Balkin teaches a tablet with a possible embodiment comprising xanthan or locust bean gum (column 4, lines 5-10; claim 17) and erythromycin or clarithromycin (column 7, lines 44-46). Balkin also teaches that the gum/organic polymer equivalent to be present in 1.5% w/w concentration, with the medicament making up 50% of the w/w of the tablet (column 4, lines 20-27; column 8, lines 30-44). Though Balkin does not claim xanthan gum as its organic polymer it is suggested and therefore leaves the claimed invention obvious. One of ordinary skill in the art would have been motivated to follow the suggestions of Balkin because of the elastic and insolubility properties of the gum chosen.

Claims 7 and 8 are drawn to the possible rate-controlling polymer, particularly the polyuronic acid salt. Claim 8 goes on to clarify that sodium alginate is the preferred polyuronic acid salt.

Urquhart et al teaches a tablet with the suggested embodiment comprising a hydrophilic hydrogel and a drug. The hydrogel is suggested to be sodium alginate (column 5, line 4-7) while the drug is suggested to be erythromycin (column 8, lines 6-14). Though Urquhart is silent to the

inclusion of derivatives of erythromycin (clarithromycin) in the suggested embodiment, the reference does teach some of the same rate controlling polymers as Balkin, which has been stated previously to be obvious over the claimed invention. Balkin and Urquhart share teachings of various carbohydrate gums as rate-controlling polymers (column 5, lines 5-10) in conjunction with erythromycin and clarithromycin. Although a cellulose polymer is claimed, these polymeric materials are art accepted as substitutable and it would have been obvious to do so at the time of the invention. One of ordinary skill in the art would have been motivated to combine the suggestions of Urquhart and Balkin because of the expandability and hydrophilicity of sodium alginate.

Claims 9 and 10 are both drawn to possible rate-controlling polymers, cellulose ethers and acrylic acid polymers respectively. As stated above Urquhart teaches a tablet with many possible interchangeable embodiment suggestions. The reference suggest the use of a hydroxypropylcellulose ether or a Carbopol ® (column 5, lines 10-18; column 6, lines 26-28) as a hydrophilic rate-controlling polymer. Urquhart's deficiencies have been previously stated, along with Balkin teachings of obviousness. One of ordinary skill in the art would have been motivated to combine the suggestions of Urquhart and Balkin because of the expandability and hydrophilicity of both hydroxypropylcellulose ether or Carbopol ®.

Claim 12 is drawn to a process for preparing a formulation of erythromycin or a derivative thereof, suitable for a single dosage, comprising a rate controlling polymer and the erythromycin. Balkin teaches, as the preferred embodiment of its tablet, the mixing of the pharmaceutical with the polymer producing a tablet (column 8, lines 48-59). Though this process is not claimed it is suggested by the specification and would have been obvious to one of

ordinary skill in the art at the time of the invention. One of ordinary skill in the art would have been motivated to follow Balkin's suggestions of mixing the polymer with erythromycin in order to maximize the interactions between the polymer and active agent.

It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings and suggestions of Balkin with the teachings of Urquhart with the expected result of a pharmaceutical tablet with antibacterial qualities and appropriate carriers for the antibacterial agent.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Razzak et al (USPN 6010718). As discussed above the reference meets the limitations of the claimed invention. It is held however that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill in the art would have been motivated to follow Example 1 in the formulation of a pharmaceutical tablet because it provides a working embodiment of a pharmaceutical tablet comprising clarithromycin and a polymer. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow Example 1 with the expected result of a pharmaceutical tablet with antibacterial qualities and appropriate carriers for the antibacterial agent.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: (a) a carbohydrate gum,

(b) a polyuronic acid salt,

(c) a cellulose ether or

(d) an acrylic acid polymer.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-5014.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
February 13, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600